SAE AS9100 Quality Systems - Aerospace Model for Quality Assurance

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Overview of AS9100

- **Adds unique aerospace requirements to ISO 9001**

- **Adds/Supplements to ISO 9001**

  essential to product, process safety and quality of aerospace

- **Contains management of "Key characteristics"**

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The Twenty ISO Elements

- 4.1 Management Responsibility
- 4.2 Quality System
- 4.3 Contract Review
- 4.4 Design Control
- 4.5 Design Output
- 4.6 Purchasing
- 4.7 Control of Customer Supplied Product
- 4.8 Product Identification and Traceability

The Twenty ISO Elements

- **4.9 Process Control**
- **4.10 Inspection and Testing**
- **4.11 Control of Inspection, Measuring and Test Equipment**
- **4.12 Inspection and Test Status**
- **4.13 Control of Nonconforming Material**
- **4.14 Corrective and Preventive Action**

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The Twenty ISO Elements

- **4.15 Handling, Storage, Packaging, Preservation and Delivery**
- **4.16 Control of Quality Records**
- **4.17 Internal Quality Audits**
- **4.18 Training**
- **4.19 Servicing**
- **4.20 Statistical Techniques**

4.1.2.4 “Process Performer”

- **Quality Assurance Activities may be delegated to the performer of that process.**
- **Procedures must define specific tasks and responsibilities which are authorized**
- **Process Performers must have corresponding requirements and training necessary to perform those tasks.**

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4.2.4 Configuration Management (CM)

- New! More detail than ISO 9001
- Requires CM of the product during its entire life cycle to ensure safety and quality.
- Process must be documented
- Encouraged to use ISO 10007 for guidance in establishing CM System

4.4.8.1 Documentation of Design Verification and Validation

- **Reports, calculations, test results, etc. must demonstrate that the product definition meets the specification requirements for all identified operational conditions and the product will function correctly.**

4.4.8.2 Design Verification and Validation Testing

- Tests shall be planned, controlled, reviewed, documented
- Test Plans identify product tested, resources used, test objectives/conditions, test parameters, acceptance criteria
- Test Procedures describe method of operation, performance of test and recording of results
- Correct configuration standard of the tested product
- Test plan requirements and procedures are observed
- Acceptance criteria is met

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4.5.3 Document and Data Changes

- **Timely review, distribution, implementation and maintenance of all authorized and released drawings, standards, specifications, planning and changes**
- **Requires a record of change incorporation**
- **Coordinate changes with customer if required**

4.6.1 Purchasing

- **“The Supplier shall be responsible for the quality of all products purchased from subcontractors, including customer-designated sources.”**

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4.6.2 Evaluation of Subcontractors

- Ensure, when required, that supplier uses customer approved special process sources.
- Ensure that Organization which Approves subcontractors have authority to disapprove them
- Review & record SubK performance, using results as basis for extent of subcontractor control
- Define (in procedures) action to take when subcontractors under-perform.

4.6.3 Purchasing Data

- **Purchasing documents shall contain:**
  - ***design, test, examination, inspection, customer acceptance requirements***
  - ***Right of access by purchaser, customer to all facilities involved***
  - ***requirements for test specimens for design approval, inspection, investigation or auditing***
  - ***requirements relative to notification of anomalies, changes in definition, and approval of their processing***
  - ***Requirements to flow down applicable requirements and key characteristics where required.***

4.6.4 Verification of Purchased Product

- **The supplier shall implement procedures to verify purchase product including:**
  - ***obtaining objective evidence of quality (documentation, CoC, test reports, statistical records, process control,etc.)***
  - ***Inspection at source***
  - ***Review of the required documentation***
  - ***Inspection of products at delivery***
  - ***delegation of verification to the subcontractor (supplier shall define the requirements for delegation and maintain a list of delegations).***

4.8 Product Identification and Traceability

- **In accordance with contract and requirements, Supplier's system shall provide for:**
  - ***Identification maintained through product life***
  - ***Traceability of all products from the same batch of raw material or manufacturing batch, as well as the destination of all products to the same batch.***
  - ***Identity of components and those of next higher assembly to be traced***
  - ***A sequential, retrievable, traceable record of production (manufacture, assembly, inspection)***
  - ***Identification of configuration of the actual product***

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4.9.1 Process Control

Controlled conditions include the following:

- **Temperature, humidity, lighting, cleanliness, etc.**
- **Monitoring and Control of Key Characteristics**
- **Accountability of all product during manufacture**
- **Evidence that all manufacturing and inspection operations have been completed as planned**
- **Provision for the prevention, detection, and removal of foreign objects**
- **Utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality**

4.9.1.1 Production Process

- **All New Requirements!**

4.9.1.1 Production Documentation

4.9.1.2 Control of Production Process Changes

4.9.1.3 Control of Production Equip, Tools & NC Machines

4.9.1.4 Control of Work Occasionally Performed Outside the Supplier's Facilities

4.9.2 Special Processes

- **Special Processes shall be identified and qualified prior to use**
- **Control applicable aspects of special processes as defined by process specs.**
- **Define the significant operations/parameters in the process to be controlled during production**

4.10.1 Inspection and Testing

- **Procedures shall include:**
  - ***Identification of authorized personnel***
  - ***Limits of authorization***
  - ***training and qualification requirements***

4.10.1 Inspection and Testing (Cont.)

- **Inspection Documentation shall include:**
  - ***Acceptance/Rejection Critera***
  - ***Sequence of inspection and testing***
  - ***Documents recording inspection results***
  - ***Identification of production/ Inspection Instruments***
  - ***Documents indicating inspection instruments are controlled***
  - ***Control of Subcontractors performing inspections***

4.10.2.4 Receiving and Testing

- When using Certification test reports, supplier shall assure data in said reports are acceptable per applicable specification.
- The supplier shall periodically validate test reports.

4.10.5 Inspection and Test Records

- **Test records shall show actual test results data when required by specification or acceptance plan.**

- **Where required to demonstrate product qualification, supplier shall ensure that quality records provide evidence that the product meets the defined requirements.**

4.10.6 First Article Inspection (FAI)

- **Supplier's system shall provide a process for inspection, verification, documentation of the first production article**
- **FAI documentation shall be retained and include design characteristics, tolerances with actual measurements and testing results**
- **FAI Inspections shall be updated to include production process changes or configuration changes**

4.11.1 Control of Inspection, Measuring & Test Equip.

- **Includes, but not limited to:**
  - ***test hardware***
  - ***test software***
  - ***Automated Test Equipment (ATE)***
  - ***Plotters use to produce inspection data***
  - ***Personally owned equipment used for product acceptance***
- **Responsibilities shall be defined regarding control of all such equipment.**

4.12. Inspection and Test Status

- **Authorized Personnel: Records shall identify personnel authorized to verify, certify and release products**
- **Acceptance Authority Media: Acceptance media (e.g. stamps, electronic signatures or passwords), shall have documented controls**

4.13 Control of Nonconforming Product

- **MRB Members: Procedures must define process**
- **Material Review Authority for UAI and Repair**
- **Regrading Material**
- **Scrap Material**
- **Notification**

4.14 Corrective Action

- **Flow-down of Corrective Action requirement to subcontractor**
- **Specific action where timely and/or effective corrective actions are not achieved**

4.15.1 Handling, Storage, Packaging, Preservation and Delivery

- **These procedures include the following:**

  Cleaning

  Prevention, detection and removal of foreign objects

  special handling for sensitive products

  marking and labeling including safety warnings

  shelf life control and stock rotation

  hazardous materials

  accompanying documents for product are present at delivery and protected.

4.17 Internal Quality Audits

- **Conduct internal quality audits that assess quality system**
- **Quality manual and working level procedures must reflect requirements of AS9100**
- **Develop tools (e.g. checklists, flowcharts, etc. to support audit of requirements**
- **Developed tools will effectively measure supplier performance**

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4.18 Training

“Training to achieve and maintain an awareness and understanding of relevant procedures and instructions shall be provided.”

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4.19 Servicing

- **When servicing is a specified requirement, suppliers procedures shall contain:**
  - ***Method of collecting and analyzing in-service data***
  - ***Actions to be taken for identified problems***
  - ***Control and updating of technical documentation***
  - ***Approval, control of repair schemes***
  - ***Required controls to work off-site (e.g. customer's facilities)***

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4.20 Statistical Techniques

- **Supplier shall develop procedures to control statistical techniques used for such things as:**
  - ***Design verification***
  - ***Process control***
  - ***Inspection***
  - ***Quality Management***
  - ***Failure Mode and Effect Analysis***